

February 10, 2003

Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road
E-79
Atlanta, GA 30333

Dear Sir or Madam:

I write on behalf of Yale University to submit comments on the interim final rule concerning the possession, use, and transfer of select agents and toxins. (67 Federal Register 76886) We appreciate the opportunity to comment on this important rule.

Yale University recognizes and accepts its responsibility to ensure the safe and secure use of select agents and toxins. Yale has an exemplary record in health and safety, and has taken steps to ensure compliance with the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness Response Act of 2002. While we commend the Department of Health and Human Services for its work in developing the interim final rule, we have several recommendations for improvements to the interim final rule.

Definition of "Access." The interim final rule does not resolve the confusion about what it means to have access to select agents and toxins. We recommend that the Department define "access" as the "Ability to gain physical control of select agents and toxins." The security plans of entities should be designed, in turn, to ensure that only those individuals authorized to have access to select agents and toxins would have access. A clear definition would help institutions to identify the list of individuals who should have access, and would also allow greater flexibility in the design of security plans. For example, a laboratory could limit access to authorized individuals by securing select agents and toxins in a locked, immovable container. It would also clarify that janitorial staff and visitors are not deemed to have access as long as the select agents and toxins are properly secured.

Ability to Conduct Research during the Transition Period. It is our understanding that persons registered under the existing Centers for Disease Control rules for shipping and receiving select agents and toxins will be permitted to continue research with select agents and toxins during the transition to the new rules over the next several months. We hope that the Department will process applications for registration and approval promptly during the transition period, thereby allowing individuals to undertake new research without undue delay. A "blackout period" for

registered individuals and entities could disrupt valuable research and would impede orderly academic planning.

Timeliness of Agency Reviews. We urge all of the federal agencies participating in the review and approval of entities and individuals to make accurate and prompt determinations about eligibility. Delays could disrupt valuable research and could prevent scientists from making adequate progress on federally funded projects. Delays could be especially problematic for students who may find themselves foreclosed from participating in a research project if their approval to conduct research involving select agents and toxins is delayed significantly.

Some delays could be avoided if individuals' approvals were portable. We recommend that an individual's clearance remain valid if the scientist moves to another institution as long as the scientist's new employer amends its registration documents promptly to include the person. We also recommend that the Department clarify that an individual's clearance will continue to be valid if his or her laboratory is relocated among any of the facilities under the oversight of the entity's Responsible Official. The change in location should, of course, be reflected in a timely amendment of the entity's registration.

Opportunity to Comment on Clearance Criteria. Considering the seriousness of the consequences for individual scientists and for University research programs, we believe the Attorney General should allow the research community an opportunity to comment on how the definition of "restricted person" will be interpreted and applied. While the Department is bound by statutory language in the respective categories, interpretation will be required to make the definitions operational. For example, will a scientist who fled political persecution in another country, and who therefore may have outstanding foreign arrest warrants against him or her, or who may have been committed to a mental institution in another country as a form of punishment, be deemed a "restricted person"? We believe the specific categories of "restricted person" should be narrowly defined in a process that is open to public comment.

Notification of Denial. We recommend that any entities or individuals denied access to select agents and toxins should be notified of the reasons for the denial. Otherwise, entities and individuals would be unable to make a meaningful request for an administrative review of their case. The notification can be given in a way that would not disclose sensitive intelligence sources about individuals.

Appeals and Waivers. We appreciate that entities and individuals denied access to select agents will be able to request an administrative review of the adverse determination against them. We hope that the reviews will be conducted thoroughly, and, if there are errors of fact or interpretation, that an adverse determination would be reversed. It is our understanding that the administrative review will be available for persons deemed ineligible under section 73.8(d)(1) and 73.8(d)(2).

We are also pleased that the Secretary of Health and Human Services will reserve the authority to allow, in exceptional circumstances, individuals deemed ineligible under 73.8(d)(2) to have access to select agents and toxins for a limited time. We recommend that the Department clarify how this provision would be invoked. Would individuals be expected to request that it be invoked? With whom should the request be made? When?

We also recommend that the Secretary also be permitted, in similarly exceptional circumstances, to permit individuals deemed ineligible under 73.8(d)(1) to have access to select agents and toxins for a limited time. It is in the national interest to take a nuanced approach that takes into account the contributions that an individual may be able to make to the country through research involving select agents and toxins. In our view there should be an opportunity for individuals and their sponsoring institutions to make the argument that the individuals have exceptional talent and insight that should be used to advance research, and that they do not present a security risk, even if they meet the criteria of a restricted person.

Span of Control. The interim final rule suggests that a Responsible Official would be unable to exercise effective oversight over an entire campus of a research university. We respectfully disagree. Institutions have found that a campus-wide programs for ensuring compliance with health and safety standards work; indeed, the centralization of oversight and reporting ensure a consistently high level of compliance and oversight across campus. A single Responsible Official also clarifies who is accountable to the campus community and the external regulatory bodies. The final regulations should allow campuses to designate Responsible Officials with responsibility for an entire campus.

"Individuals Who Own or Control." The interim final rule requires the registration of "any individual who owns or controls the entity." We understand this to mean, in the case of a research university, that the senior administrators to whom the Responsible Official reports must be named in the university's registration; we do not construe this to require an application for approval for members of the board of trustees. The final

Freedom of Information Act Requests. The interim final rule calls for the collection of considerable information about individuals, the select agents and toxins being used on a campus, and the location of those samples. The Department should ensure that this information not be available through Freedom of Information Act requests.

Thank you for the opportunity to comment on the interim final rule.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Dorothy K. Robinson".

Dorothy K. Robinson